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EXAMINER				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/731,316

**Applicant(s)**

FAVUZZI ET AL.

**Examiner**

P. Kathryn Wright

**Art Unit**

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**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 49-79, 81-83 and 86-90 is/are pending in the application.
- 4a) Of the above claim(s) 49-68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 69-79, 81-83 and 86-90 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of the Claims***

1. This action is in response to papers filed January 25, 2008 in which claims 69, 76, 86-87, and 90 were amended and claim 80 was canceled. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated September 04, 2007 are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection, necessitated by the amendments, are discussed.

Claims 49-68, 84-85 and 91-98 are withdrawn. Claims 69-79, 81-83, 86-90 are currently under prosecution.

### ***Drawings***

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "sample immerser element" and "slide immerser element" must be shown or the features canceled from the claims. No new matter should be entered. Applicant states at page 15 of the Reply, filed January 25, 2008, the "sample immerser element" is illustrated in Figs. 7-10 by reference numeral "101" which denotes a "fluid containment element" or "dip tank" in which the vertically disposed slides 7v may be immersed.

The Examiner disagrees this cited disclosure is sufficient. The specification should be amended to include the sample immerser element corresponds to reference no. 101. Otherwise, claims 69 and 86 should be amended to recite "a fluid containment element including a slide immerser element..."

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction

of the following is required: "sample immerser element" and "slide immerser element" in claim 69 and 86.

The rules of the PTO require that application claims must "conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description." See 37 CFR 1.75(d)(1).

#### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 69-79, 81-83 and 86-90 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 69 and 86 now recite " a sample immerser element including a slide immerser element for submerging a substantially vertically disposed slide with said at least one tissue sample in at least one fluid..."

First as pointed out above, it is not clear what elements in the figures or the specification correspond to the "sample immerser element" the "slide immerser element". For example, Applicant states at page 15 of the Reply, filed January 25, 2008, the "sample immerser" is illustrated in Figs. 7-10 by reference numeral "101" which denotes a "fluid containment element" or "dip tank" in which the vertically

disposed slides 7v may be immersed. Claims 75, 76, 78, 79, 83, 87-89 depend from independent claims 69 and 86. Claims 75, 76, 78, 79, 83, 87-89 recite "a fluid containment element". Therefore, the claims contain both the "sample immerser element" and the "fluid containment element". Thus, it appears that Applicant is attempting to claim the same element under different names (i.e., sample immerser element and fluid containment element"). Applicant is reminded that the recitation of the same element under different names in different parts of the claim or the use of same term to refer to different elements is indefinite. The same term should be used for an element each and every time it is recited.

Furthermore, it is not clear how the sample immerser element includes a slide immerser element. As discussed by Applicant the sample immerser corresponds a fluid containment element or dip tank 101, see instant specification at page 10, lines 20-24. This is confusing since claim 76 which recites the "slide immerser element is adapted to lower said slide into said fluid containment element". How does the slide immerser element both correspond to the fluid containment element and lower into the fluid containment element? Clarification is required.

In addition, the specification does not clarify what is meant by the "sample immerser element" or the "slide immerser element". The part of the specification that discusses the "slide immerser" merely defines it as the act of immersing, see page 15, lines 4-11. Therefore it is not possible to determine the metes and bounds of the claims as currently written.

Claims 69-79, 81-83 and 86-90 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: between the sample immerser element and the slide immerser element. How is the "sample immerse element" structurally connected to the "slide immerser element"?

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 69-73, 75-79, and 86-90, as best understood, are rejected under 35 U.S.C. 102(b) as being anticipated by Wilkie et al. (US Patent no. 4,092,952), (hereinafter "Wilkie").

Wilkie teaches an automatic strainer system for staining at least one tissue sample. Specifically, Wilkie teaches a slide S having said at least one tissue sample disposed thereon and a reagent application element (91, stain container) which apply reagent to the at least one tissue sample when the slide is disposed substantially horizontally (see for example col. 3, lines 60+ and Fig. 2).

Wilkie also teaches a sample immerser element (e.g., slide rack 193) for immersing (submerging) a plurality of slides having the at least one tissue sample in at least one fluid for application to the at least one tissue sample during at least one pre-treatment operation performed on the at least one tissue sample prior to the staining operation. The sample immerser element also includes a slide immerser element and slide positioner element 207, 215, 225 to lower the slide into the fluid containment elements containing fluid (e.g., 43, 79) and rotate the slide to a substantially vertical disposition and back into the fluid containment elements (see, for example, col. 5, lines 49+ and Figs. 2-4).

Note that the slide immerser element rotates and submerges a substantially vertical slide (see Fig. 2). That is, the claim language does not require the slide be vertically disposed when submerged rather the slide immerser element submerge the once vertically disposed slide into the fluid. The Wilkie slide is vertically disposed at one point and the slide immerser element and slide positioner element 207, 215, 225 are able to rotate the slide between the substantially vertical position shown in Fig. 2 to a horizontal position in the fluid containment elements (see, for example, col. 5, lines 49+ and Figs. 2-4). Therefore, the claim limitations are met.

As to claim 75 and 78, the slide-drying chamber 43 (one fluid containment element) includes a heating element 45 (electric resistance heater).

Claims 70-73 and 86 describe the manner in which the staining apparatus is intended to be employed. Please note that a recitation with respect to the manner in which a claimed apparatus is intended to be employed, (i.e., pre-treatment operation,



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target retrieval, removal of an embedding medium, etc.) fails to differentiate the claimed apparatus from a prior art apparatus if the prior art apparatus teaches all the structural limitations of the claim.

With respect to claim 79, Wilkie teaches a pneumatic element (pump 59) adapted to transfer liquid from a supply tank 51 to a transfer tank (filter tank 101) to the fluid containment element (rinse tank 79; Fig. 4) and to a drain element (87; Fig. 5) which removes the liquid from the fluid containment element to the transfer tank and the waste collection tank at outlet 109.

Regarding claim 88, the phrase "dip tank" does not include any structural limitations which would serve to distinguish from the fluid containment elements (e.g., 43, 79) of Wilkie.

### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
11. Claims 74, and 81-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilkie (US Patent no. 4,092,952) in view of Copeland et al. (US Patent no. 5,595,707), (hereinafter "Copeland").

The teachings of Wilkie have been summarized previously above. Wilkie does not explicitly recite the use of at least one slide rack configured to accommodate one slide and a drawer assembly that includes at least one slide rack and is adapted to retract from the system.

Copeland teaches an automatic strainer system for staining at least one tissue sample. Copeland teaches, *inter alia*, a rotating slide rack 24 configured to accommodate a plurality of slides 26 and a drawer assembly 22 "adapted to" retract from the system, wherein the drawer assembly comprises the slide rack on the top surface. Note that the phrase "drawer assemblies" does not include any structural limitations which would serve to distinguish from the plates 22, 40 of Copeland. Giving

the claims the broadest reasonable interpretation, the Examiner takes the position that the drawer assemblies of Copeland are "adapted to retract from the system" when disassembled as shown in Fig. 2. In addition, the drawer assemblies "cooperates with" the fluid containment elements 12, hot supply tank 44, transfer tank 50, and waste tank 58 in that the drawers support these elements when mounted on top of their respective drawer assemblies (see Fig. 2). USPTO personnel are to give claims their broadest reasonable interpretation in light of the supporting disclosure.

Accordingly, it would have been obvious to one having ordinary skill in the art to include in the apparatus of Wilkie, the slide rack and drawer assembly of Copeland, since the slide rack provides a means to process multiple slides at a time, thereby increasing analyzer throughput.

### ***Response to Arguments***

12. Applicant's arguments filed January 25, 2008 have been fully considered but they are not persuasive.

Applicant's arguments in response to the previous rejection of claims 69-75, 78, 81-83 and 86-90 under 35 U.S.C. 102(b) as being anticipated by Copeland (US Patent no. 5,595,70) have been considered but are moot in view of the new grounds of rejection set forth above.

Regarding the previous rejection of claims 69-73, 75-79, and 86-90, under 35 U.S.C. 102(b) as being anticipated by Wilkie (US Patent no. 4,092,952), Applicant argues that Wilkie does not disclose a sample immerser element including a slide

immerser for submerging a substantially vertically disposed slide with at least one tissue sample in at least one fluid.

The Examiner respectfully disagrees. Wilkie teaches a sample immerser element (e.g., slide rack 193) for immersing (submerging) a plurality of slides having the at least one tissue sample in at least one fluid for application to the at least one tissue sample during at least one pre-treatment operation performed on the at least one tissue sample prior to the staining operation. The sample immerser element includes a "slide immerser element" and "slide positioner element" 207, 215, 225 to lower the slide into the fluid containment elements containing fluid (e.g., 43, 79) and rotate the slide to a substantially vertical disposition (see, for example, col. 5, lines 49+ and Figs. 2-4). Note that the slide immerser element of Wilkie rotates and submerges a substantially vertical slide (see Fig. 2) to a horizontal position. The claim language does not require the slide vertically disposed when submerged. The slide of Wilkie is vertically disposed at one point and the slide immerser and slide positioner elements 207, 215, 225 rotate the slide between a substantially vertical position shown in Fig. 2 to a horizontal position in the fluid containment elements for submersion (see, for example, col. 5, lines 49+ and Figs. 2-4). Therefore, Wilkie meets all the limitations of claims 69 and 86.

### ***Conclusion***

13. No claims are allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

1. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Wright whose telephone number is (571)272-2374. The examiner can normally be reached on Monday thru Thursday, 9 AM to 6 PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

May 19, 2008

pkw

/Jill Warden/  
Supervisory Patent Examiner, Art Unit 1797